

Maintenance doses average 2 to 4 mg. daily. After achieving satisfactory control the patient should be switched to oral therapy as soon as feasible.

The dose for intrasynovial administration is usually 4 mg. for large joints and 0.8 to 1 mg. for small joints. For soft tissue and bursal injections a dose of 2 to 4 mg. is recommended. Ganglia require a dose of 1 to 2 mg. A dose of 0.4 to 1 mg is used for injection into tendon sheaths and helomata. Injections into inter-vertebral joints should not be attempted at any time and hip joint injection cannot be recommended as an office procedure.

Intrasynovial and soft tissue injections should be employed only when affected areas are limited to 1 or 2 sites. It should be remembered that corticoids provide palliation only and that other conventional or curative methods of therapy should be employed when indicated.

Supplied—5-cc (4 mg/cc) multiple dose vial; 1-cc (4 mg/cc) vial, box of 25.

LAKESIDE LABORATORIES,
Milwaukee, Wis., November 1967.

DEAR DOCTOR: The Food and Drug Administration have requested that we call your attention to the monograph for Norpramin (desipramine hydrochloride) in the 1967 PDR: page 687, white section. The FDA consider this monograph incomplete (in relation to the official labeling, the package insert), and therefore potentially misleading as prescribing information to allow safe and effective use of the drug.

To provide you with the necessary adequate reference, we enclose a revised monograph for 1967 Physicians' Desk Reference in which the changes have been emphasized by italics. Please insert this revision opposite page 687.

Sincerely yours,

WILLIAM C. JANSSEN, M.D.

(Insert opposite p. 687—PDR, 1967 edition)

(NOTE.—Prescribing information for Norpramin which appears in the 1967 edition of PDR has been revised. The following is the new monograph and completely replaces the old one. Changes are emphasized by means of italics.)

NORPRAMIN

(Desipramine hydrochloride)

Composition: Norpramin (desipramine hydrochloride) (10, 11-dihydro-5-(3-methylaminopropyl)-5H-dibenz [b, f] azepine hydrochloride), available in two dosage sizes: 25 mg. tablet, round, sugar coated, yellow; 50 mg. tablet, round, sugar coated, light green.

Action and Indications: Norpramin (desipramine hydrochloride) is a primary active metabolite of imipramine. It differs from earlier antidepressants in its rapid onset of action. Approximately 60 to 70% of patients with neurotic or psychotic depressions will respond satisfactorily. More than half will begin to improve in 2-5 days, others within a week. Usually, patients not responding within one week are less likely to improve. Norpramin is useful in the treatment of neurotic and psychotic depressive reactions, and in manic depressive or involutional psychotic reactions. It may be used as co-therapy with tranquilizers in the treatment of markedly agitated forms of depressions.

Contraindications: (1) Norpramin should not be given in conjunction with or within two weeks of treatment with a monoamine oxidase inhibitor. (2) Because of its physiologic effects (both anticholinergic and epinephrine potentiating), it is contraindicated in patients with glaucoma, urethral or ureteral spasm and recent myocardial infarction. (3) *The presence of severe coronary heart disease with EKG abnormalities indicating a progressive disability and symptoms of heart failure due to this disability is likewise a contraindication.* (4) Active epilepsy as it lowers the threshold for epileptiform seizures.

Warnings (Relative Contraindications): *Palpitations, due to tachycardia, have been observed with desipramine hydrochloride therapy. Desipramine hydrochloride should be given therefore to patients with a history of paroxysmal tachycardia only with awareness that palpitations may be induced. In some such patients, the myocardium may not be in condition to tolerate well the increased work and decreased perfusion incident to such paroxysms.*